# HOW INNOVERE ACCELERATED THEIR PATH TO MARKET BY IMPLEMENTING AN EQMS PURPOSE BUILT FOR MEDICAL DEVICE COMPANIES

Advanced magnetic resonance imaging (MRI) technology has become an important piece of healthcare that millions of patients experience daily.

Innovere is on a mission to improve the patient experience associated with MRI's. One major limitation they had to face was a lack of in-house medical device expertise that was hindering their ability to establish a compliant QMS that would enable their team to scale product development efforts in an efficient manner.

After identifying the need for a medical device quality management system, Innovere was determined to find a QMS partner that could enhance their team's industry knowledge and accelerate their path to commercialization.

## INNOVERE SETS OUT TO IMPROVE THE MRI EXPERIENCE FOR PATIENTS

More than 30 million patients in the United States alone enter a dark, tight, and noisy space for anywhere from 15 to 90 minutes when getting an MRI. For many, this is an isolating and somewhat frightening experience that can lead to significant patient discomfort associated to the MRI experience.

Innovere's Innovision™ device provides patients with visual entertainment and advanced sound quality to increase overall comfort during an MRI by addressing common discomforts, such as, anxiety and boredom. The creation of such a device is not as simple as it may seem due to the complexity of MRI technology. Innovere has successfully built a device that is safe for use in an MRI and does not interfere with the scan or images produced.

## OVERCOMING THE QMS CHALLENGE WITH NO INDUSTRY EXPERIENCE ON-HAND

Lynsie soon discovered that being classified as a medical device company meant:

- Complying with quality and regulatory standards for a medical device company
- Implementing a quality management system
- Abiding to quality system standards like ISO 13485

Heading into her search for a QMS, Lynsie's primary question was, ***"How can we implement a quality system that people will actually use?"***

Lynsie and her team began exploring different options for establishing a QMS, but came to find that many companies were using **completely paper-based systems,** which ***"just felt wrong"*** to her and her team. Lynsie stated, *"I knew that if it was a paper-based binder process, people [at Lucerno] wouldn't use it."*

innOvere

**HQ:** Markham, Ontario, Canada

**Device Classification:** Class I

**End Market:** USA

**Previous Solution:** None

**Greenlight Guru Champion:** Lynsie Thomason, Regulatory & Operations Lead at Innovere

> ***WE KNEW WE WOULD NEED SOME HAND-HOLDING AS WE WEREN'T EXPERIENCED IN THE REGULATORY AFFAIRS SIDE OF THINGS. WE WANTED SOMETHING WE COULD LEARN AND GROW OUR OWN EXPERTISE FROM.***

**Lynsie Thomason,**
Regulatory & Operations Lead at Innovere

## GETTING GREENLIGHT GURU UP AND RUNNING

Without any burdensome configuration or prolonged implementation process, Innovere was taking full advantage of the software in ***just a few weeks***.

From their one-on-one sessions with Customer Success Team Member and Industry Guru, Jesseca Lyons, the Innovere team was equipped to fully leverage the software and get up to speed quickly on design control and risk management activities that are critical when commercializing safe and effective medical devices.

Lynsie shares that Greenlight Guru's Customer Success team was highly engaged and responsive to their needs throughout their implementation

## AUDIT SUCCESS LEADING TO A NEW PARTNERSHIP

The true value of implementing Greenlight Guru became apparent for Innovere during their first audit that was conducted by the Supplier Quality Department of a potential partner – and one of the largest MRI manufacturers.

Given that this was their first time going through a medical device audit performed by a third party, Lynsie recalls that the team experienced a ***truly*** **paperless audit** and confidently answered questions regarding their QMS thanks to Greenlight Guru.This was largely attributed to built in controls and traceability gained by using Greenlight Guru's fully connected medical device quality management software. Also, the knowledge attained by leveraging the expertise of Greenlight Guru's Customer Success Team so they knew what to expect during their audit was huge advantage for Innovere.

Ultimately, using Greenlight Guru's software and expertise allowed them to experience a very successful and seamless audit. Lynsie shared that the prospective partner's supplier quality team was thoroughly impressed by Innovere's fully digital QMS that included automatic revision control, audit trails, Part 11 compliant signatures, and system validation. They also had positive remarks about the system's full traceability between their design controls and risk management matrices.

This successful audit ultimately led to a commercial partnership agreement for Innovere.

## GREENLIGHT GURU: A QMS PARTNER TO COUNT ON

As a long standing Greenlight Guru customer, Lynsie's primary reasons for recommending Greenlight Guru are:

- The software is 100% cloud-based – providing a truly digital QMS with full traceability and simplified validation efforts enabling the Innovere team to maintain a low total cost of ownership of the system.
- The built-in medical device controls and supporting industry knowledge base is invaluable.

### REASONS FOR CHOOSING GREENLIGHT GURU

After assessing several eQMS options, Innovere ultimately decided on Greenlight Guru. What convinced them that it was the best solution?

Greenlight Guru's software contained everything they needed to:

- Meet their eQMS requirements
- Help navigate medical device quality and regulatory requirement
- Educate their team and grow their own expertise throughout their path to market by leveraging the Guru Services offered by Greenlight Guru

> ***"WITH GREENLIGHT GURU, YOU'VE GOT SOFTWARE, BUT ALSO WHAT AMOUNTS TO A PERSONAL CONSULTANT. THOSE CONNECTIONS ARE POWERFUL."***
>
> *Lynsie Thomason, Regulatory & Operations Lead at Innovere*

Between the capabilities of the quality management software platform itself and the industry experts at Greenlight Guru, the team at Innovere has gained the valuable knowledge necessary for navigating the medical device industry's complex quality and regulatory environment. Leveraging this partnership with Greenlight Guru has enabled Innovere to grow their own expertise and accelerate their path to commercial success for the first of many devices intended to positively impact patient experiences.